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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/787,045

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John Hatlestad

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EXAMINER

RANGREJ, SHEETAL

ART UNIT

PAPER NUMBER

3626

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/787,045	<b>Applicant(s)</b> HATLESTAD ET AL.	
	<b>Examiner</b> SHEETAL R. RANGREJ	<b>Art Unit</b> 3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-11, 13, 14 and 16-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11, 13-14, and 16-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Prosecution History Summary***

- Claims 12 and 15 are cancelled.
- Claims 1, 9, 11, and 24-25 are amended.
- Claims 1-11, 13-14, and 16-28 are pending.

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/11/2008 has been entered.

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-11, 13-14, and 16-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yarin et al. (U.S. Patent No. 6,294,999) in view of LaPorte et al. (U.S. Publication No. 2005/0182389).

3. As per claim 1, Yarin teaches a medication storage, therapy, and consumption management system, comprising:

- a containment unit configured to accessibly house diuretic medication (**Yarin: figure 3**);

- a health management host system coupled to the containment unit in a manner that allows data transmission (**Yarin: figure 9**);

- said containment unit including communications and control system that records and transmits data relating to a medication event, said containment unit control system further providing for transmitting and receiving medication therapy data (**Yarin: figure 9**);

- said health management host system configured to receive data related to the medication event (**Yarin: col. 10, 53-62**), receive physiologic data (**Yarin: col. 9, 56-62**), analyze, and display the patient physiologic data and the medication event data on a health management display (**Yarin: col. 11, 27-32**), and generate a diuretic medication therapy regimen using the analysis of the patient physiological data and the medication event data (**Yarin: col. 12, 11-20**).

Yarin, however, fails to expressly teach a medication storage, therapy, and consumption management system, comprising: an implantable device configured to implantably electrically monitor fluid retention; and receiving patient physiological data including fluid retention data collected by the implantable device.

Nevertheless, these features are old and well known in the art as evidenced by LaPorte. In particular, LaPorte teaches a medication storage, therapy, and consumption management system, comprising: an implantable device configured to implantably electrically monitor fluid retention; and receiving patient physiological data including fluid retention data collected by the implantable device (**LaPorte: para. 41; para 43**).

One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of Yarin with the teachings of LaPorte with the motivation that therapeutic substance therapy in conjunction with the activities and information obtained by an implanted medical device is an important consideration in the overall treatment of a patient (**LaPorte: para. 7**).

4. As per claim 2, Yarin teaches wherein the patient physiological data comprises weight, fluid retention data, data monitored by an implantable device and neuro-hormonal data (**Yarin: fig. 8; col. 5, 49-64; col. 6, 35-44**). The examiner interprets that measurements relating to weight, fluid retention data, data monitored by an implantable device, and neuro-hormonal data are included in the data gathered by various appliances.

5. As per claim 3, Yarin teaches wherein the containment unit is further configured to communicate wirelessly with said health management host system (**Yarin: figures 1-2**).

6. As per claim 4, Yarin teaches wherein the containment unit is configured with a display device to illustrate a medication therapy strategy (**Yarin: fig. 12; col. 6, 29-35**).

7. As per claim 5, Yarin teaches wherein the containment unit is configured to receive data from an external source and further configured to transmit such data to the health management host system (**Yarin: col. 11, 28-33**).

8. As per claim 6, Yarin teaches wherein the containment unit is further configured to notify the patient when it is time to take the medication housed therein (**Yarin: col. 10, 63-64**).

9. As per claim 7, Yarin teaches wherein the containment unit is further configured to communicate a request for a medication re-fill with a pharmacy system when the quantity of the medication is below a pre-determined level (**Yarin: col. 3, 41-50**).

10. As per claim 8, Yarin teaches wherein said health management host system processes said data related to the medication event data and said patient physiological data, and in response thereto provides for the generation of an updated medication therapy regimen (**Yarin: col. 11, 11-26**).

11. As per claim 9, Yarin teaches an electronic patient health management system, comprising:

- a medication therapy management device, configured to house diuretic medication and store data related to patient consumption of medication (**Yarin: col. 3, 37-40**), the medication therapy management device further configured for interrogating the medical measurement device and processing the data retrieved from the medical measurement[[s]] device and the data related to patient consumption of medication (**Yarin: col. 11, 5-10; col. 11, 34-47**); and
- a patient wellness host system, communicatively coupled to the medication therapy management diagnostic device, configured to receive and display the processed data (**Yarin: col.**

**11, 20-23)** and use the processed data to generate a diuretic medication therapy regimen (**Yarin: figure 8**).

Yarin, however, fails to expressly teach an electronic patient health management system, comprising: -an implantable medical measurement device for implantably electrically measuring data related to at least one patient physiological health factor including fluid retention data.

Nevertheless, these features are old and well known in the art as evidenced by LaPorte. In particular, LaPorte teaches an electronic patient health management system, comprising: -an implantable medical measurement device for implantably electrically measuring data related to at least one patient physiological health factor including fluid retention data (**LaPorte: para. 41; para. 43**).

The motivation to combine the teachings is the same as claim 1.

12. As per claim 10, Yarin teaches wherein the medication therapy management diagnostic device is further configured to provide a reminder to a patient when it is time to take the medication (**Yarin: col. 10, 63-64**).

13. As per claim 11, Yarin teaches comprising an external medical measurement device for measuring data related to at least one patient physiological health factor (**Yarin: col. 11, col. 3, 51-65**).

14. As per claim 13, Yarin teaches wherein the medical measurement electronic diagnostic device is communicatively coupled to the patient wellness host system via an Internet connection (**Yarin: col. 3, 41-50**).

15. As per claim 14, Yarin teaches wherein the medical measurement electronic diagnostic device is communicatively coupled to the patient wellness host system via a wireless communication link (**Yarin: col. 3, 41-50; col. 6, 3-5**).

16. As per claim 16, Yarin teaches wherein data related to the at least one patient physiological health factor comprises data monitored by an implantable device (**Yarin: fig. 8; col. 5, 49-64; col. 6, 35-44**).

17. As per claim 17, Yarin teaches wherein data related to the at least one patient physiological health factor comprises weight data (**Yarin: fig. 8; col. 5, 49-64; col. 6, 35-44**).

18. As per claim 18, Yarin teaches wherein data related to the at least one patient physiological health factor comprises neuro-hormonal data (**Yarin: fig. 8; col. 5, 49-64; col. 6, 35-44**).

19. As per claim 19, Yarin teaches wherein data related to the at least one patient physiological health factor comprises renal function data (**Yarin: fig. 8; col. 5, 49-64; col. 6, 35-44**).

20. As per claim 20, Yarin teaches further configured to process said data received in order to develop and display a therapeutic response (**Yarin: col. 11, 11-26**).

21. As per claim 21, Yarin teaches wherein the developed therapeutic response comprises revising medication regime (**Yarin: col. 11, 48-54**), maintaining current medication regime (**Yarin: col. 3, 36-40**), and recommending a diet plan (**Yarin: col. 11, 40-47**).



22. As per claim 22, Yarin teaches wherein the patient wellness host system is a computer, which comprises with a memory (**Yarin: col. 7, 3-5**), a processor (**Yarin: col. 6, 45-48**) and a user interface (**Yarin: col. 6, 26-28**).

23. As per claim 23, Yarin teaches wherein the medication diagnostic device communicates with the patient wellness host system to alert the wellness manager that the medication level is below a pre-determined level (**Yarin: col. 5, 42-46**).

24. As per claim 24, Yarin teaches a method for remote management of a medication therapy using a medication containment unit, the method comprising:

-alerting a patient when it is time to carry out diuretic medication step of a first therapeutic plan (**Yarin: col. 10, 53-64**);

-sensing when the medication containment unit is engaged and recording the same as a medication event (**Yarin: col. 9, 21-41; col. 11, 5-10**);

-receiving patient physiological data (**Yarin: col. 5, 49-54**);

-processing said patient physiological data and said medication event data (**Yarin: col. 11, 34-47**); and

-generating a second therapeutic plan in response to said processing of said patient physiological data and said medication event data (**Yarin: col. 11, 34-47**).

Yarin, however, fails to expressly teach a method for remote management of a medication therapy using a medication containment unit, the method comprising: implantably electrically sensing fluid retention data; and receiving patient physiological data including the implantably-sensed fluid retention data.

Nevertheless, these features are old and well known in the art as evidenced by LaPorte. In particular, LaPorte teaches a method for remote management of a medication therapy using a medication containment unit, the method comprising: implantably electrically sensing fluid retention data (**LaPorte: para. 41; para. 43**); and receiving patient physiological data including the implantably-sensed fluid retention data (**LaPorte: para. 41; para. 43**).

The motivation to combine the teachings is the same as claim 1.

25. As per claim 25, Yarin teaches wherein the alerting step comprises notifying the patient to consume at least one of medication (**Yarin: col. 10, 53-64**).

26. As per claim 26, Yarin teaches wherein the alerting step comprises causing the medication containment unit to generate one of the following, an audible sound, to vibrate and to communicate with a second external device which responsively prompts the patient to act (**Yarin: col. 8, 43-48**).

27. As per claim 27, Yarin teaches wherein the receiving step is initiated by an external device transmitting patient physiological data to the containment unit (**Yarin: col. 5, 49-54**).

28. As per claim 28, Yarin teaches wherein the receiving step is initiated when the containment unit interrogates an external device (**Yarin: col. 5, 49-54**).

***Response to Arguments***

29. Applicant's arguments with respect to claims 1-11, 13-14, and 16-28 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

30. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

31. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHEETAL R. RANGREJ whose telephone number is (571) 270-1368. The examiner can normally be reached on M-F 8:30-5:30.

32. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry O'Connor can be reached on (571) 272-6787. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

33. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private

PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or (571) 272-1000.

/SRR/  
Patent Examiner  
September 25, 2008

/Gerald J. O'Connor/  
Supervisory Patent Examiner  
Group Art Unit 3626